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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,622	06/19/2001	Coenraad Jan Spaans	POLYGANICS-1	8926

7265 7590 05/14/2002
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EXAMINER

GORR, RACHEL F

ART UNIT	PAPER NUMBER
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1711

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DATE MAILED: 05/14/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

T.D-7

Office Action Summary

Application No.

09/701,622

Applicant(s)

SPAANS ET AL

Examiner

Rachel Gorr

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17-33 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 17-33 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

1. The Disclosure is missing a "Brief Description of the Drawings". See MPEP 608.01f.

2. Claim 32 provides for the use of a polyurethane, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 32 is rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

3. Claim 29 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 29 contains the same limitations as claim 28.

4. Claims 20-26, 30 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 23 and 26, the word "caprolactone" is misspelled.

Claims 21, 22, 26 and 33 are indefinite for not setting forth the metes and bounds of the claims. These claims contain both broad limitations and narrower limitations. The narrower limitations begin with the word "preferably". (10 USPQ2d 2031, 2033)

Claim 20 is confusing because the preceding claims doesn't have an antecedent basis for "E" or "XYX".

Claim 30 is confusing because the preceding claim has no antecedent basis for "random copolymer".

Claim 24 is confusing because it repeats the ingredient "diethylene glycol" twice.

In claim 25, the word "obtainable" should be changed to "obtained" to make the claim more definite. Claim 25 isn't understood because it's directed to a process of reacting an excess of OH groups versus NCO groups, and then further reacting with water. There would be no functional groups present capable of reacting with water?

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claim 27 is rejected under 35 U.S.C. 102(b) as being anticipated by Ozaki.

Ozaki discloses a diol that can be made from a mole of tetramethylene diisocyanate and two moles of butane diol (See circled structure, and CAS reg. No. 15887-14-6). The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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7. Claims 17-22, 28, 29, 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Groot (New Biomedical Polyurethane ureas...) in view of Cohn and de Groot (Use of porous...).

8. De Groot (New Biomedical Polyurethane...)discloses polyurethanes made from caprolactone polyester polyols and butane diisocyanate (see summary). He shows making polyurethanes having a homogeneous block structure. The polyester is reacted with an excess of diisocyanate (top page 212) and the excess unreacted diisocyanate is removed to make a polyester terminated with two diisocyanates. He uses these polyurethanes for medical applications. He differs from the claims by chain extending the prepolymer with a diamine rather than with a diol, and by not showing porous polyurethanes or the specific application of meniscal reconstuction.

9. Cohn teaches that polyurethanes for biodegradable medical applications can be chain extended with diamines or diols. (col. 4, lines 1-18)

10. De Groot (Use of...) discloses using porous polyurethanes for meniscal reconstruction.

11. It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute a diol for the diamine of de Groot because Cohn teaches that these polyurethanes are more easily dissolved or melt processed for shaping medical articles. It would have been obvious to make the polyurethane porous and use it for meniscal reconstruction because de Groot (Use of...) discloses this as an application of medical polyurethanes.

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12. Claims 17, 18, 20, 21, 24, 28, 29 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Quay.

Quay discloses polyurethanes having homogeneous block structure. He makes prepolymers from polyester polyols (col. 3, lines 59-64) and diisocyanate and chain extends with a diol (col. 4, lines 38-50). He makes the prepolymer with excess diisocyanate and then removes the unreacted excess diisocyanate (see the examples). This enables the formation of homogenous prepolymer comprising the polyester terminated with the diisocyanates.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The other references listed on the PTO-892 form are those references cited in the foreign search report.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rachel Gorr whose telephone number is (703) 308-3608. The examiner can normally be reached on Mon.-Fri., from 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jim Seidleck can be reached on (703) 308-2462. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9310 for regular communications and (703) 872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.


RACHEL GORR
PRIMARY EXAMINER